

Serial No.: 10/804,596

Docket No.: 905.020US2

Filed: March 18, 2004

Title: INTRODUCER HAVING A MOVABLE VALVE ASSEMBLY WITH REMOVABLE SIDE PORT

REMARKS

This responds to the Office Action mailed on July 7, 2006.

Claims 17, 26 – 28, 31, 32, and 34 are amended; claims 17-40 are now pending in this application.

§112 Rejection of the Claims

Claims 17-25 and 26-34 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description or enablement. Claims 26-34 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description or enablement, with respect to “the side port coupling member releasably coupled with the sheath coupling member along the sheath hub” in claim 26. Applicant respectfully traverses the rejection and submits the enabling and adequate description can be found, among other places, at pages 13 – 14, and Figures 10 – 12 of the application. Reconsideration and allowance are respectfully requested.

§103 Rejection of the Claims

Claims 35-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Scarfone et al. (US 5,300,046) in view of West et al. (US 6,322,541). Claims 38-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Scarfone in view of West (as applied to claim 37 above), and further in view of Trinder (US 2,493,326). Claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Scarfone in view of West (as applied to claim 35 above), and further in view of Dressel (US 5,102,410).

Applicant respectfully traverses the rejections. The cited references fail to establish all of the elements of claims 35 - 40. For instance, Applicant cannot find in Scarfone, West, Trinder, or Dressel, or in combination thereof, the method of uncoupling a side port assembly from a coupled position, as recited in claim 35, from which claims 36 – 40 depend. Furthermore, Applicant cannot find in the cited references, sealing the side port of the introducer with the side

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port valve after removing the side port assembly, as recited in claim 35, from which claims 36 - 40 depend.

Notwithstanding the fact that all elements cannot be found in the cited references, Applicant further traverses the rejection because the cited references are not enabling. The cited references fail to enable a side port assembly that is releasably coupled with the sheath, uncoupling the side port assembly from the coupled position, and sealing the side port of the introducer with the side port assembly from the coupled position, and sealing the side port of the introducer with the side port valve after the side port assembly is removed from the coupled position (as recited in claims 35 – 40).

Furthermore, the Office Action fails to provide an objective motivation to combine the references. Notwithstanding that the references fail to establish all of the elements of the claims as discussed above, Applicant submits the Office Action fails to establish a *prima facie* of obviousness, because there is no *objective* motivation to combine the references. According to the Office Action “it would have been obvious . . . since the use thereof would provide a more flexible and durable usage on an introducer application,” or “would provide an improved fluid flowing control method, in an introducer application,” or “it would have been obvious . . . since the use thereof would provide an improved method to prevent fluid leak from an introducer.” Office Action, Pages 4-5.

As the Federal Circuit has stated: “Virtually all inventions are combinations of old elements. . . . If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.” *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal Inc.*, 56 U.S.P.Q.2d 1641, 1644 (Fed. Cir. 2000), quoting *In re Rouffet*, 149 F.3d 1350, 1357-1358, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998).

Instead, motivation to combine the references must be found in the prior art, and not based on Applicant’s disclosure. Furthermore, a showing of a suggestion, teaching, or motivation to combine prior teachings “must be clear and particular . . . Broad conclusory

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statements regarding the teaching of multiple references, standing alone, are not ‘evidence.’” *In re Dembiczak*, 175 F.2d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

Applicant notes that no objective support is provided for any of these assertions and instead the Office Action uses the claims as a template and selectively uses elements from various references, declaring it an “improvement”. While Applicant agrees that the claims involve an improvement over the art, the Office Action fails to establish a legally sufficient nor objective motivation to so selectively combine the references. In fact, it appears the Office Action is relying on the personal knowledge of the Examiner. Applicant requests an affidavit supporting the assertions as required by 37 CFR 1.104(d)(2). Applicant further traverses the assertion under MPEP 2144.03 or removal of the unsupported assertion and removal of the rejection. Reconsideration and allowance of the claims are respectfully requested.

Claims 35-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker et al. (US 5,755,693) in view of Scarfone, and further in view of West. Claims 38-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker in view of Scarfone, further in view of West (as applied to claim 37 above), and further in view of Trinder. Claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker in view of Scarfone, further in view of West (as applied to claim 35 above), and further in view of Dressel).

Applicant respectfully traverses the rejection because all of the elements cannot be found in the cited references. For instance, Applicant cannot find in Walker, Scarfone, or West, or in combination thereof, the method of uncoupling a side port assembly from a coupled position, as recited in claim 35, from which claims 36 – 40 depend. Furthermore, Applicant cannot find in the cited references, sealing the side port of the introducer with the side port valve after removing the side port assembly, as recited in claim 35, from which claims 36 - 40 depend.

Notwithstanding the fact that all elements cannot be found in the cited references, Applicant further traverses the rejection because the cited references are not enabling. The cited references fail to enable a releasable side port assembly that is releasably coupled with the sheath. The references are silent as to this issue.

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Furthermore, the Office Action fails to provide an objective motivation to combine the references. Notwithstanding that the references fail to establish all of the elements of the claims as discussed above, Applicant submits the Office Action fails to establish a *prima facie* of obviousness, because there is no *objective* motivation to combine the references. According to the Office Action “it would have been obvious . . . since the use thereof would provide a more flexible and durable usage on an introducer application,” or “would provide an improved fluid flowing control method, in an introducer application,” or “it would have been obvious . . . since the use thereof would provide an improved method to prevent fluid leak from an introducer.” Office Action, Pages 6-8.

Applicant notes that no objective support, for example *any* support from the cited references, is provided for any of these assertions and instead the Office Action uses the claims as a template and selectively uses elements from various references, declaring it an “improvement”. While Applicant agrees that the claims involve an improvement over the art, the Office Action fails to establish a legally sufficient or objective motivation to so selectively combine the references. In fact, it appears the Office Action is relying on the personal knowledge of the Examiner. Applicant requests an affidavit supporting the assertions as required by 37 CFR 1.104(d)(2). Applicant further traverses the assertion under MPEP 2144.03 or removal of the unsupported assertion and removal of the rejection. Reconsideration and allowance of the claims are respectfully requested.

Remarks regarding “Response to Arguments”

According to the response to Arguments on pages 8 and 9, “the teaching of West reference is to utilize a snap-fit connection or threaded connection, to releasably couple a side port assembly (20) to a hemostasis valve . . . with an additional seal valve (26) inbetween to seal the side port of the introducer after the side port assembly is removed from the coupled position.” Applicant cannot find any support in West for such an assertion; there is no support the specification nor in the drawings in West for these assertions. Applicant requests an affidavit supporting the assertions as required by 37 CFR 1.104(d)(2). Applicant further traverses the

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assertion under MPEP 2144.03 or removal of the unsupported assertion and removal of the rejection. Reconsideration and allowance of the claims are respectfully requested.

Reservation of Right to Swear Behind References

Applicant reserves the right to swear behind any references which are cited in a rejection under 35 U.S.C. §§102(a), 102(e), 103/102(a), and 103/102(e). Statements distinguishing the claimed subject matter over the cited references are not to be interpreted as admissions that the references are prior art.

AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.116

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

MICHAEL LANGE ET AL.

By their Representatives,

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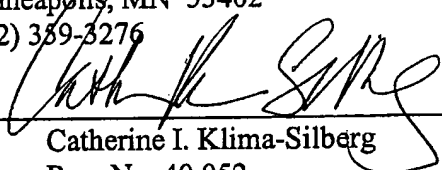
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Date

Oct. 10, 2006

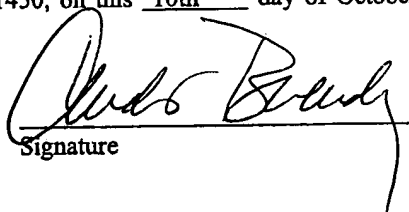
By


Catherine I. Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10th day of October, 2006 (Tuesday after Federal holiday).

CANDIS BUENDING

Name


Signature